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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
06/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/936,362	LOOSMORE ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 19-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16,17 and 19-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 4/6/09 is made. Claims 16, 17 and 19-22 are currently pending.

Claim Rejections - 35 USC § 112, 2nd paragraph

1. Claims 16, 17 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 has been amended into an improper Markush Group since the phrase 'selected from the group consisting of..." has been deleted from the claim. Accordingly, the claim reads as if all parts (a)-(d) are part of the composition. Yet, it is unclear how all components could be part of the composition since it is to a cell transformed with a single vector. Are all of these sequences part of a fusion? The claim is vague and confusing as amended. A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). The claim no longer recites 'selected from the Group consisting of…" which appears to be an error. Appropriate correction is requested.

Claim 16, part (c), is vague and indefinite because it is unclear what protein would result from the pair of amplifiers set forth in SEQ ID Nos: 60 and 18. Applicants have stated that these are sense and antisense primers, for amplifying the strain 33 hia gene from the V38 codon to the the SnaBI site, which sequence corresponds to

nucleotides 131-179 in Figures 18A-B. These arguments have been fully and carefully considered, but are not deemed persuasive. The claim is drawn to a strain of E.coli which has been transformed by an expression vector comprising a nucleic acid. The nucleic acid itself should be recited in the claim. The term 'amplifiable' does not set forth the actual sequence which is part of the claim. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. Appropriate correction is requested.

Claim 16, part (d), is vague and indefinite because the mere recitation of a name, i.e., the V38 N-truncated H.influenzae adhesion protein of NTH strain 33, to describe the DNA which is used to encode the claimed polypeptide invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or the nucleic acid sequence of the DNA encoding the protein, which would allow for one to identify the protein without ambiguity. The mere recitation of a name of the protein or DNA does not adequately define the claimed protein. Applicants argue that read in view of the specification, the meaning of the phrase would be clear to one of skill in the art. This has been fully and carefully considered but is not deemed persuasive. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in

and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. Appropriate correction is requested.

The preamble of claim 16 recites that the recombinant protein is 'producible' by the recited strains transformed with the recited vectors. However, this language renders the claim vague and indefinite because it is not equated with 'being produced by' which leads the claim vague and indefinite because having the capability of being produced by a vector is not the same thing as actually performing the function. A positive recitation of the function is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 16, 17 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "An immunogenic composition comprising a recombinant protective H.influenzae adhesion (Hia) protein of non-typeable strain 33 of H.influenzae which is produced by a strain of E.coli which has been transformed with an expression vector comprising an isolated and purified nucleic acid molecule having the DNA sequence shown in SEQ ID NO: 23 or an isolated and purifed nucleic acid molecule which encodes the protein having the amino acid sequence shown in SEQ ID NO: 24" (e.g., parts (a) and (b) of claim 16), does not reasonably provide enablement for the immunogenic compositions comprising the

polypeptides from parts (c), or (d) of claim 16. The specification also does not enable protective compositions or methods of protection of disease caused by Haemophilus (which includes any species).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

When considering a bacterial antigen as a vaccine candidate, three major considerations must be raised (1) the antigen must be conserved among strains of the bacterial species whose disease one wishes to prevent; (2) it must generate protective antibody such that the antibody to the antigen prevents disease; and (3) it must be a good immunogen such that protective antibodies are elicited in the population at risk and that these antibodies persist for sufficient time to provide protection throughout the risk period (Murphy et al. Pediatr. Infect. Dis. J. 1989. 8: S66-S68). Even when an antigen meets these three considerations, further testing often indicates that the antigen will not be effective as a vaccine. For example, Murphy et al. Pediatr. Infect. Dis. J. 1989. 8: S66-S68, teach that P6 is an important vaccine candidate based on these considerations, but Yamanaka et al (J. Pediatrics. 1993. 122(2): 212-218) later demonstrated that the population at most risk did recognize P6 as an antigen. The instant specification fails to demonstrate that any of the polypeptides recited in parts (a)-(d) of claim 16 meet any of the three considerations known in the art to be important when considering a bacterial antigen as a vaccine candidate. Without specific guidance from the specification, it would take undue experimentation for those skilled in the art to

make and/or use the claimed invention. Additionally, the claims17, 21 and 22 are drawn to protecting disease caused by any species of Haemophilus yet the polypeptides are from *H.influenzae*. It is unclear that the polypeptides of the claimed compositions would be able to provide protection against a different species of Haemophilus. It is unclear that these proteins are found in any other species of Haemophilus, especially other pathogens, such as *Haemophilus ducreyi*. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." Accordingly, the specification does not enable vaccines to protect against disease caused by Haemophilus, or methods of inducing protection against disease caused by any species of Haemophilus.

The specification also does not enable the scope of the polypeptides set forth in parts (c)-(d) of claim 16. As stated above, the claims do not adequately describing and setting forth the inventive concept. The claims should provide any structural properties, such as the amino acid sequence of the protein or molecular weight along with function,

which would allow for one to identify the protein without ambiguity. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. The specification only enables the polypeptide set forth in SEQ ID NO: 24 or one encoded by the nucleic acid sequence set forth in SEQ ID NO: 23. It does not enable variants of these sequences.

Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Response to Applicant's Arguments:

Applicants argue that Example 13 demonstrates that administration of the V38 rHia protein to in chinchillas resulted in partial protection from challenge by the NTHi strain 33 and therefore, the V38 rHia (33) was show to provide protection in an accepted model of vaccination against H.influenzae. These arguments have been fully and carefully considered but are not deemed persuasive because they are not commensurate in scope with the claimed invention which encompasses protection

against disease caused by any species of Haemophilus, e.g., including other pathogens, such as *Haemophilus ducreyi*. It is unclear and unpredictable whether the polypeptides of the claimed compositions would be able to provide protection against a different species of Haemophilus. It is unclear that these proteins are found in any other species of Haemophilus. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

Status of Claims

4. The prior art does not teach a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 or a polypeptide which is encoded by the nucleic acid sequence set forth in SEQ ID NO: 23. Immunogenic compositions comprising these polypeptides and methods of raising an immune response using these polypeptides are free of the prior art and would be allowable.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

6/8/09